DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1185B

BUFFALO DISTRICT
Food and Drug Administration
599 Delaware Avenue
Buffalo, NY 14202

11 February 1997

WARNING LETTER BUF 97-12

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Michael J. Klamm, Owner/President
Electric Beach Limited
5701 East Circle Drive
Cicero, NY 13039

Dear Mr. Klamm:

An inspection of your tanning salon at 5701 E. Circle Drive, Cicero, NY 13039, was performed 9-15 January 1997 by Food & Drug Administration Investigator Gifford Whitehurst, Jr. The inspection revealed serious violations of the Food, Drug & Cosmetic Act (the Act) and the Federal Performance Standards for Sun Lamp Products, as prescribed in Title 21, Code of Federal Regulations, Part 1040.20 (21 CFR 1040.20) regarding operation of your tanning beds.

These violations were included in the FDA-483, Notice of Inspectional Observations, issued to and discussed with you at the conclusion of the inspection.

The inspection revealed your four tanning beds, manufactured by [redacted], are adulterated within the meaning of Section 501(h) of the Act, because the [redacted] sunlamps, [redacted] being used in the beds are not compatible/equivalent to the [redacted] and [redacted] sunlamps designated for the beds. The [redacted] sunlamps in use emit over four times the UVB radiation emitted by the [redacted] sunlamps designated for the tanning beds. An acceptable method of correction includes replacing the [redacted] sunlamps with sunlamps designated by the manufacturer and/or sunlamps that are equivalent. The tanning beds may also be recertified for use with alternate lamps. Simply reducing exposure time from 30 minutes to 20 minutes, without recertification of the tanning beds, is not acceptable.

The [redacted] tanning beds are also misbranded within the meaning of Section 502 (f) of the Act, because they did not bear labeling provided by the manufacturer which includes warning and danger statements, recommended exposure schedule, maximum exposure time, lamp type, certification statements and manufacturers' information [CFR 1040.20 (d) (1) (i-vi) & 1040.20(d)(3)(i)]. All labels required by the regulations should be permanently affixed to the tanning beds and remain permanently affixed to the tanning beds.

Finally, the required instruction manuals for your tanning beds are inadequate/incomplete because they do not provide adequate direction for use to avoid or minimize potential injury to the user from harmful exposure to ultraviolet radiation [CFR 1040.20 (e) (1)(i-v)]. An acceptable correction would be to obtain instruction manuals that provide adequate directions for use, including appropriate technical and safety information as required by the regulations, and have them available to the user.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure electronic sunlamp products in use at your tanning salon meet applicable performance standards and are in compliance with the provisions of the Act.

You should take prompt action to correct these and all violations at your firm. The four [redacted] tanning beds should be removed from use until appropriate corrective action is taken. Failure to take such action may result in regulatory action, such as seizure, injunction and/or civil penalties, **without further notice.**

Please notify this office, in writing, within 15 days, of the <u>specific</u> steps you have taken, or intend to take, to correct these violations. Your response should be directed to:

Joseph H. Erdmann, Team Leader
Food & Drug Administration
P.O. Box 7197
Syracuse, NY 13260

Sincerely,

Irving Weitzman

Irving Weitzman
Acting District Director

emz